

P.O. Box 1001
Norwich, Vt 05055

December 21, 1999

1449 00 JAN -3 AM 126

Dockets Management Branch
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

I am the Medical Director of the Assisted Reproductive Technology Program at the Dartmouth Hitchcock Medical Center, in Lebanon, NH. am writing in reference to Docket # 97N-484S. Suitability Determination for Donors of Human Cellular and Tissue Based Products.

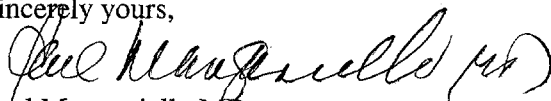
I was dismayed to read of the proposed rule requiring the freezing of donor embryos up to 6 months before transfer into the recipient, to test for infectious diseases in the donor.

I oppose this arbitrary regulation, because there is now no scientific justification. As far as I am aware, there are no reports of infectious diseases being spread, including HIV, despite numerous IVF-ET procedures.

By requiring freezing the embryos, will decreasing their overall chance of survival, thereby increasing costs to the patients, as well as increasing the emotional burden. It has been estimated that over 9,000 embryos will be lost per year, which would be a terrible loss of potential human life.

Thank you for your time and consideration of my concerning, and hope that the ruling can be amended

Sincerely yours,



Paul Manganiello MD
Associate Professor
Department of Obstetrics and Gynecology
Dartmouth Hitchcock Medical Center

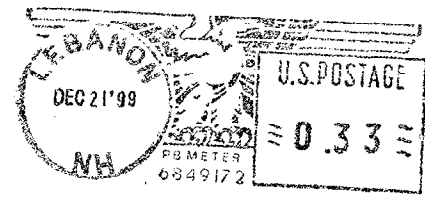
97N 484S

C 369



Dartmouth-Hitchcock Medical Center

One Medical Center Drive
Lebanon, New Hampshire 03756



2523

Dockets Management Branch
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

20852/9999

